UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

IN RE: Bair Hugger Forced Air Warming Products Liability Litigation	MDL No. 2666 (JNE/FLN)
This Document Relates to **ALL ACTIONS**	

DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE THE TESTIMONY OF ANTONIA HUGHES, RN, BSN, MA, CNOR

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INTRODUCTION

Plaintiffs' motion to exclude the expert opinion testimony of Antonia Hughes, RN, BSN, MA, CNOR, should be denied. Plaintiffs' challenges to Ms. Hughes' extensive qualifications and the foundation for her opinions are perfunctory and largely boilerplate. In some instances, Plaintiffs' attacks are based on outright misrepresentations: for example, Plaintiffs claim, falsely, that Ms. Hughes has no experience with the Bair Hugger system even though she states in her report that she has experience with it in ***hundreds*** of operations.

Ms. Hughes' testimony focuses on important material issues in this case and will aid the trier of fact. Plaintiffs and their experts maintain that the Bair Hugger system is the most likely cause of any surgical infection that develops following a total joint procedure. Underlying their opinions are the premises that operating rooms are essentially sterile and that nothing other than the Bair Hugger system has an effect on the flow of air in the operating room. Drawing on her decades of clinical experience in the operating room during surgical procedures, Ms. Hughes rebuts these premises. She explains that, despite robust infection prevention measures, operating rooms are clean, not sterile, environments. The filtered air in the operating room is not considered sterile, and is not sterile over the operating surgical table. Wiping down operating room equipment with a disinfectant does not kill all bacteria on the equipment. A patient's own skin, not rendered sterile after being scrubbed with antiseptic solutions, is a source of bacteria. Likewise, many other pieces of equipment *brought close to the surgical field* are sources of bacteria. Moreover, other

devices commonly used in operating rooms contain fans that blow air into the operating room.

The sources of bacteria in the operating room during a surgical procedure, and equipment and devices that may affect the airflow in an operating room, are matters beyond a layperson's common knowledge and are appropriate subjects of expert testimony. *See, e.g.*, *Manerchia v. Kirkwood Fitness & Racquetball Clubs, Inc.*, 2010 WL1114927, at *3 (Del. Mar. 25, 2010) (recognizing that "the identification of the source of bacteria is a matter that requires an understanding and analysis of issues beyond the ken of the typical jury"). Indeed, Ms. Hughes is the only nurse designated by either side, further underscoring the usefulness of her testimony to the trier of fact.

In short, Ms. Hughes is well qualified by her decades of clinical experience as a certified operating room nurse to offer the opinions in her report. Plaintiffs' motion should be denied.

ARGUMENT

I. MS. HUGHES, A CERTIFIED OPERATING ROOM NURSE, IS HIGHLY QUALIFIED TO TESTIFY ON THE OPERATING ROOM ENVIRONMENT DURING ORTHOPEDIC SURGICAL PROCEDURES.

There can be no serious dispute that Ms. Hughes is qualified to offer expert opinions on the sterility (or lack thereof) of the operating room and instruments, equipment and devices used in total joint procedures.

Ms. Hughes has a bachelor of science in nursing degree and is certified as an operating room nurse. Pl. Mem. at 2. Ms. Hughes' expert report details her more than 35 years of experience as an operating room nurse, including her experience as a scrub nurse

assisting surgeons in total joint procedures and as an RN circulator who manages the operating room during total joint procedures. DX1, Hughes Rpt. at 1.[1] As Ms. Hughes explains, the scrub nurse assists the surgeon during the surgical procedure and "monitor[s] the sterile field." *Id.* An RN circulator manages the operating room and the entire surgical team during the surgery. *Id.*

In addition to Ms. Hughes' bachelor of science in nursing degree, her certification as an operating room nurse, and her many years of training and clinical experience in the operating room, Ms. Hughes has served on the Association of periOperative Registered Nurses (AORN) Committee for Standards in Perioperative Nursing, has made presentations to nurses on AORN Guidelines, and educates nurses on AORN recommended practices for a safe environment of care for patients. DX1 at 2. She has published an article on the implementation of AORN recommended practices for a safe environment of care. *Id.*

Based on this extensive clinical and professional association experience, Ms. Hughes has knowledge, education, training and experience in: (i) what constitutes the surgical field in the operating room, (ii) what operating room equipment is used during a total joint surgical procedure and is brought near the surgical field and operating room table where the patient is placed, (iii) what operating room equipment brought near the surgical field – and thus close to the patient – is not considered sterile, (iv) whether skin prep

[1] All citations to "DX" in this memorandum are to the exhibits to the Declaration of Deborah E. Lewis in Opposition to Plaintiffs' Motion to Exclude the Testimony of Defendants' Expert Antonia Hughes, filed concurrently with this memorandum.

solutions (antiseptic solutions) render a patient's skin sterile, (v) what operating room equipment near the surgical field also has an internal fan, (vi) whether disinfectant solutions used to wipe down equipment in the operating room will eliminate all bacteria, and (vii) the placement of the Bair Hugger blanket on the patient. DX1 at 3-6. These are all material issues relating to the cause[2] of surgical infections, and will be at issue in each and every case.

Contrary to Plaintiffs' assertion, Ms. Hughes has not limited her expert opinions to one statement that operating rooms are not sterile. Pl. Mem. at 1. Instead, her expert opinions, as described above, will help explain to the trier of fact the numerous aspects of the operating room environment, including air movement, during orthopedic surgical procedures.

Moreover, Plaintiffs' assertion that Ms. Hughes has not used the Bair Hugger system is simply wrong and misleading. Pl. Mem. at 9. As Ms. Hughes explains in her expert report, "[i]n [her] many years of experience as a nurse in the operating room, the Bair Hugger device has been used on hundreds of surgical patients to assist with maintaining normal body temperature before, during and after surgical procedures." DX1 at 6. In other words, the Bair Hugger system has been used (the blanket being placed on the patient by the circulating nurse and regulating/monitoring of the system being

[2] Ms. Hughes is not offering an expert opinion on the cause of surgical site infections.

administered by anesthesia personnel) in hundreds of surgical procedures in which Ms. Hughes has participated as circulating nurse.[3]

II. MS. HUGHES' TESTIMONY IS RELEVANT AND RELIABLE.

A. Ms. Hughes' Opinions Rebut Key Premises of Plaintiffs' Claims.

Ms. Hughes' opinions respond directly to the arguments advanced by Plaintiffs and their experts. Plaintiffs' experts maintain that the Bair Hugger system is the most likely source of bacteria causing surgical infections. Koenigshofer Rpt at 3, 4 [ECF No. 839 (DX35 to Declaration of Peter J. Goss)]; David Rpt at 6 [ECF No. 316]; Stonnington Rpt at 4 [ECF No. 751-1 (DX6 to Declaration of Benjamin W. Hulse)]; Jarvis Rpt at 8 [ECF No. 751-1 (DX4 to Declaration of Benjamin W. Hulse)]; Samet Rpt at 13 [ECF No. 751-1 (DX2 to Declaration of Benjamin W. Hulse)]. Ms. Hughes responds, based on her extensive clinical experience, that several pieces of operating room equipment other than the Bair Hugger system contain bacteria because they are not sterile. DX1 at 3. Disinfectants used to wipe down equipment do not kill all bacteria, thus equipment brought near the surgical field and close to the patient contain bacteria. *Id.* She further notes that other devices and equipment in operating rooms during total joint surgical procedures contain internal fans and such pieces of equipment are used near the surgical field. *Id.* In fact, she states that one is able to feel air coming out of the anesthesia machine, cautery device, computer monitors and hard drives. DX2, Hughes Dep. at 125:25–126:2; 127:6-8;

[3] The deposition testimony Plaintiffs cite asked questions about "settings" on the Bair Hugger system, things the anesthesiologist, rather than the nurse, would regulate. It is not evidence that Ms. Hughes does not use the Bair Hugger system.

128:8-10; 129:18-21. Again, these items – that blow air – Ms. Hughes has identified as not sterile. DX1 at 3. Ms. Hughes' opinion that the operating room air is not sterile rebuts Koenigshofer's statement in his report that there is a "waterfall of sterile air" from an operating room's ventilation system. ECF No. 839 at 8.

In rebutting Plaintiffs' theories on the sterility of the operating room environment, Ms. Hughes points out the flaws in these theories, and need not develop independent theories and conclusions. As this Court has recognized, "[i]t is the proper role of rebuttal experts to critique plaintiffs' expert's methodologies and point out potential flaws in the plaintiff's expert's reports." *Aviva Sports, Inc. v. Fingerhut Direct Marketing, Inc.*, 829 F. Supp. 2d 802, 834 (D. Minn. 2011), *quoting Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748, 759 (8th Cir. 2006). Ms. Hughes may offer pure critique, rather than independent theories and conclusions, and her opinions should still be admissible. *Id.*, *quoting In re Cessna 208 Series Aircraft Prods. Liab. Litig.*, MDL No. 1721, 2009 WL 1649773, at *1 (D. Kan. June 9, 2009) (a rebuttal expert who critiques another expert's theories or conclusions need not offer his own independent theories or conclusions).

B. Ms. Hughes' Expert Opinions Will Assist the Trier of Fact.

Ms. Hughes' expert opinions will aid the trier of fact in understanding numerous issues not within a layperson's general and common knowledge about an operating room environment in which surgical procedures are performed. For example, it is not within a lay person's common knowledge that a patient's skin, after being scrubbed with an antiseptic solution, is not sterile because all bacteria are not killed. *See, e.g.*, *Manerchia*, 2010 WL1114927, at *3 (recognizing that "the identification of the source of bacteria is a

matter that requires an understanding and analysis of issues beyond the ken of the typical jury"); *Offshore Pipelines, Inc. v. Schooley*, 984 S.W.2d 654, 665 (Tex. App. - Hous. [1st Dist.] 1998, no pet.) ("[T]he jury needed no scientific guidance except to the extent that Dr. Soloway provided help in understanding the nature of the Yersinia bacteria and the means by which it is typically transmitted."). Underscoring this point, the 1999 CDC Guideline for Prevention of Surgical Site Infection has reminded professionals in the healthcare field that "[f]or most SSIs, the source of pathogens is the endogenous flora of the patient's skin, mucous membranes, or hollow viscera. When mucous membranes or skin is incised, the exposed tissues are at risk for contamination with endogenous flora." DX3, Ex 5 to deposition of Dr. William Jarvis, publication entitled Mangram, A. et al., "Guideline for prevention of surgical site infection, 1999," 27 *American Journal of Infection Control* 97 (1999).

Likewise, it is not common knowledge among laypersons what equipment is within the operating room and used during a total joint procedure, what equipment is brought near the surgical field, whether the equipment brought near the patient is covered with sterile drapes, and whether equipment near the surgical field is considered sterile. DX1 at 3-5. It is not common knowledge among laypersons that the air from the ventilation system entering the operating room above the surgical site (surgical incision) is not considered sterile. DX1 at 2.

Plaintiffs' allegations in the case are about surgical infections. These and other issues about the operating room environment, which Ms. Hughes addresses in her expert report, require the opinion of an expert witness to help the trier of fact understand. *See, e.g.*,

U.S. Surgical Corp. v. Orris, Inc., 983 F. Supp. 963, 966–67 (D. Kan. 1997) (permitting nurse to offer expert opinion "that disposable medical instruments cannot be adequately recleaned and resterilized" based on "her thirty years of experience, including her operating room experience in which she has seen numerous unclean and/or faulty reused instruments, her employment experience in which she established a testing program to verify the effectiveness of recleaning and resterilizing, and her consulting experience in which she has visually examined recleaned and resterilized instruments"); *Williams v. Eighth Judicial Dist. Court of State, ex rel. Cty. of Clark*, 262 P.3d 360, 367 (Nev. 2011) (finding registered nurse with "extensive experience in cleaning and disinfecting the type of equipment used during an endoscopy procedure . . . more than qualified to testify as to proper cleaning and sterilization procedures for endoscopic equipment"); *Smith v. Hrynkiw*, No. 2:05-CV-1759-VEH, 2008 WL 8700457, at *10 (N.D. Ala. Apr. 28, 2008) (permitting nurse to testify as expert under Rule 702 and *Daubert* "in the area of positioning and turning patients receiving surgical care").

C. Ms. Hughes Relied on Appropriate Authorities.

In addition to her many years of knowledge, education, training and experience in the operating room during total joint surgical procedures, Ms. Hughes can rely on industry-recognized authorities and publications such as AORN, and other peer-reviewed articles as the bases of some of her opinions. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("Trained experts commonly extrapolate from existing data."); *See* Fed. R. Evid. 703 ("An expert may base an opinion on facts or data *in the case that the expert has been made aware of* or personally observed.") (emphasis added); *Daubert v. Merrell Dow Pharms., Inc.*, 509

U.S. 579, 592 (1993) ("Unlike an ordinary witness, an expert is permitted wide latitude to offer opinions, *including those that are not based on firsthand knowledge or observation*.") (emphasis added). Not only has Ms. Hughes identified the materials considered for the opinions in her expert report, in addition to her extensive knowledge, education and clinical experience in the operating room, her sources considered include AORN publications (including official guidelines) and scientific articles from peer-reviewed journals. DX1 at 7.

Thus, Plaintiffs' boilerplate assertion that Ms. Hughes' opinions are not based on facts, data or methodology, simply ignores what she says in her report. Furthermore, the cases Plaintiffs cite are distinguishable. For example, in *American Family Mut. Ins. Co. v. Kline,* 780 F.Supp.2d 839, 842 (2011), policy holders brought a breach of contract action against an insurance carrier following a house fire. The policy holders' expert witness listened to the 911 call following the fire, created an enhanced version of the 911 recording, and developed a transcript of the conversations within the call. *Id.* The insurance carrier moved to exclude the expert witness from testifying about the identity and content of conversations on the recording as well as the transcript created by the expert. The insurance carrier contended that the transcript was just a statement of who said what on the recording. *Id.* The jurors could listen to the 911 recording and reach their own conclusions. The court agreed and limited the testimony of the expert witness because his testimony would not help the jurors since they could listen to and interpret themselves the 911 recording. *Id.* at 842-843. The other case Plaintiffs cite, *Lee v. Andersen,* 616 F.3d 803, 809 (8th Cir. 2010), involved an expert who enhanced video images captured by a surveillance camera and who

concluded that the suspect who was killed by a police officer did not have a gun in his hand moments before the shooting. The Eighth Circuit affirmed the exclusion of the expert's opinion holding that the jurors were capable of analyzing the images on the video and determining whether the suspect had anything in his hands. *Id.*

Neither case is similar to the opinions Ms. Hughes has offered. Ms. Hughes is not offering opinions about a video or recording that jurors can see or hear with their own eyes or ears. To the contrary, her opinions involve more complex issues about bacteria, sources of bacteria in the operating room, sterility, and what equipment is used during surgical procedures, issues well beyond the common knowledge of laypersons. *Manerchia*, 2010 WL1114927, at *3; *Schooley*, 984 S.W.2d at 665.

D. Ms. Hughes Is Not Engaged in "Biased Advocacy."

Plaintiffs contend that Ms. Hughes acts as an improper "advocate" for Defendants. Pl. Mem. at 8. Their sole support for this allegation is on page 4 of Ms. Hughes' report, where she states that "[r]esearch has shown forced-air warming devices to be safe for use in the operating room." DX1 at 4. Plaintiffs conveniently leave out the "[r]esearch has shown" part of this statement and attempt to suggest that Ms. Hughes is offering an opinion on Bair Hugger safety. Not only does Ms. Hughes cite the AORN reference for this statement in her report, she also made clear during her deposition that she was not herself offering expert opinions on the safety and efficacy of the Bair Hugger. DX2, at 167:19-168:3. A factual statement about what research has shown – indeed, a factual statement that has been supported by numerous independent healthcare organizations, including AORN and the FDA – is not partisanship, and in any event is not an expert opinion for

which Ms. Hughes has been offered. Defendants have offered several other experts who do offer this opinion.

III. MS. HUGHES' OPINIONS ARE GENERALLY ACCEPTED UNDER MINN. R. EVID. 702.

Minn. R. Evid. 702 states that a qualified expert's opinions and testimony are admissible if they have both: (1) foundational reliability, and (2) general acceptance in the relevant scientific community. *Goeb v. Tharaldson*, 615 N.W.2d 800, 814 (Minn. 2000). *See also McDonough v. Allina Health Sys.*, 685 N.W.2d 688, 696 (Minn. App. 2004) (affirming the district court's determination that plaintiff's expert's general causation theory is not generally accepted). As detailed above, Ms. Hughes' opinions are appropriately based on her extensive professional knowledge, education and clinical experience in the operating room and her review of the scientific literature. Unlike Plaintiffs' experts' opinions, her conclusions are generally accepted in the scientific and nursing communities. Furthermore, as noted above, Ms. Hughes cites AORN Guidelines for many of her opinions. And the 1999 CDC Guidelines make clear how for most surgical site infections, the source of bacteria is a patient's skin, mucous membranes or hollow viscera. DX3 at 103. As such, Ms. Hughes' opinions are admissible in the Minnesota state cases.

CONCLUSION

Ms. Hughes' expert testimony and opinions are admissible under Fed. R. Evid. 702 and Minn. R. Evid. 702. Her testimony rebuts Plaintiffs' experts on key issues concerning the sources of bacteria in the operating room. It will assist the trier of fact in understanding

the environment in which orthopedic surgical procedures are performed and the environment in which the Bair Hugger system is used. Plaintiffs' motion to exclude Ms. Hughes' testimony should be denied.

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Respectfully submitted,

/s/ Deborah E. Lewis

Jerry W. Blackwell (MN #186867)
Deborah E. Lewis (MN #0397922)
Benjamin W. Hulse (MN #0390952)
Mary S. Young (MN #0392781)
BLACKWELL BURKE P.A.
431 South Seventh Street, Suite 2500
Minneapolis, MN 55415
Phone: (612) 343-3248
Fax: (612) 343-3205
Email: blackwell@blackwellburke.com
dlewis@blackwellburke.com
bhulse@blackwellburke.com
myoung@blackwellburke.com

Bridget M. Ahmann (MN #016611x)
FAEGRE BAKER DANIELS LLP
2200 Wells Fargo Center
90 South Seventh Street
Minneapolis, MN 55402
Phone: (612) 766-7000
Fax: (612) 766-1600
Email: bridget.ahmann@faegrebd.com

Counsel for Defendants 3M Company and Arizant Healthcare Inc.